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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,002	05/20/2005	Ugur Sahin	GMD-102.1P US	7473
7590	01/11/2006		EXAMINER	
Leon R Yankwich Yankwich & Associates 201 Broadway Cambridge, MA 02139			LIETO, LOUIS D	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/537,002	SAHIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Louis D. Lieto	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-28, 32-40, 42-67, 69-71, 73-78, 82-94 and 98 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-28, 32-40, 42-67, 69-71, 73-78, 82-94, and 98 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I claim(s) 1-3, drawn to a pharmaceutical composition, comprising an agent which inhibits the expression or activity of a tumor associated antigen, wherein said antigen has a sequence encoded by a nucleic acid.

Group II, claim(s) 1-3, drawn to a pharmaceutical composition, comprising an agent which inhibits the expression or activity of a tumor associated antigen, wherein said antigen has a sequence encoded by the complement of the nucleic acid.

Group III, claim(s) 1-4,10,24,27, and 28, drawn to a pharmaceutical composition, comprising an agent which is an antisense nucleic acid which hybridizes with the nucleic acid encoding for the tumor associated antigen.

Group IV, claim(s) 1-4,10,24,27, and 28, drawn to a pharmaceutical composition, comprising an agent which is an antisense nucleic acid which hybridizes with the complement of the nucleic acid encoding for the tumor associated antigen.

Group V, claim(s) 1-3, 5,6,10,20-23, 27 and 28, drawn to a pharmaceutical composition, comprising an antibody which inhibits the expression or activity of a tumor associated antigen, wherein said antigen has a sequence encoded by a nucleic acid.

Group VI, claim(s) 1-3, 5,6,10,20-23, 27 and 28, drawn to a pharmaceutical composition, comprising an antibody which inhibits the expression or activity of a tumor associated antigen, wherein said antigen has a sequence encoded by the complement of a nucleic acid.

Group VII, claim(s) 7,8,10,25,26,27,28,32, drawn to a pharmaceutical composition, comprising an agent which inhibits the expression or activity of a tumor associated antigen, wherein said antigen has a sequence encoded by a nucleic acid, wherein said agent comprises the tumor associated antigen or a part thereof.

Group VIII, claim(s) 7,8, 10,11,12,27,28, drawn to a pharmaceutical composition, comprising an agent which inhibits the expression or activity of a tumor associated antigen, wherein said antigen has a sequence encoded by a nucleic acid, wherein the agent comprises a nucleic acid which codes for the tumor-associated antigen or a part thereof.

Group IX, claim(s) 7,8,10,13-19,27,28, drawn to a pharmaceutical composition, comprising an agent which inhibits the expression or activity of a tumor associated antigen, wherein said antigen has a sequence encoded by a nucleic acid, wherein the agent comprises a host cell which expresses for the tumor-associated antigen or a part thereof.

Group X, claim(s) 7,8,10,27,28, drawn to a pharmaceutical composition, comprising an agent which inhibits the expression or activity of a tumor associated antigen, wherein said antigen has a sequence encoded by a nucleic acid, wherein the agent comprises an isolated complex between the tumor-associated antigen or a part thereof and an HLA molecule.

Group XI, claim(s) 7,8,10,25,26,27,28,32, drawn to a pharmaceutical composition, comprising an agent which inhibits the expression or activity of a tumor associated antigen, wherein said antigen has a sequence encoded by the complement of the nucleic acid, wherein said agent comprises the tumor associated antigen or a part thereof.

Group XII, claim(s) 7,8, 10,11,12,27,28, drawn to a pharmaceutical composition, comprising an agent which inhibits the expression or activity of a tumor associated antigen, wherein said antigen has a sequence encoded by the complement of the nucleic acid, wherein the agent comprises a nucleic acid which codes for the tumor-associated antigen or a part thereof.

Group XIII, claim(s) 7,8,10,13-19,27,28, drawn to a pharmaceutical composition, comprising an agent which inhibits the expression or activity of a tumor associated antigen, wherein said antigen has a sequence encoded by the complement of the nucleic acid, wherein said antigen has a sequence encoded by a nucleic acid, wherein the agent comprises a host cell which expresses for the tumor-associated antigen or a part thereof.

Group XIV, claim(s) 7,8,10,27,28, drawn to a pharmaceutical composition, comprising an agent which inhibits the expression or activity of a tumor associated antigen, wherein said antigen has a sequence encoded by the complement of the nucleic acid, wherein said agent comprises the tumor associated antigen or a part thereof.

Group XV, claim(s) 9,27,28, drawn to a pharmaceutical composition comprising two or more agents.

Group XVI, claim(s) 33,34,35,36,37-39, 53-55, drawn to a method of diagnosing a disease, comprising detecting a nucleic acid, which encodes a tumor associated antigen, wherein said antigen has a sequence encoded by a nucleic acid.

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Group XVII, claim(s) 33,34,35,36,40,42, 53-55, drawn to a method of diagnosing a disease, comprising detecting a tumor associated antigen, wherein said antigen has a sequence encoded by a nucleic acid.

Group XVIII, claim(s) 33,34,35,36, 53-55, drawn to a method of diagnosing a disease, comprising detecting an antibody to a tumor associated antigen, wherein said antigen has a sequence encoded by a nucleic acid.

Group XIX, claim(s) 33,34,35,36, 53-55, drawn to a method of diagnosing a disease, comprising detecting a cytotoxic or T helper lymphocyte specific to the tumor associated antigen, wherein said antigen has a sequence encoded by a nucleic acid.

Group XX, claim(s) 33,34,35,36,37-39, 53-55, drawn to a method of diagnosing a disease, comprising detecting a nucleic acid, which encodes a tumor associated antigen, wherein said antigen has a sequence encoded by the complement of the nucleic acid.

Group XXI, claim(s) 33,34,35,36,40,42, 53-55, drawn to drawn to a method of diagnosing a disease, comprising detecting a tumor associated antigen, wherein said antigen has a sequence encoded by a nucleic acid.

Group XXII, claim(s) 33,34,35,36, 53-55, drawn to drawn to a method of diagnosing a disease, comprising detecting an antibody to a tumor associated antigen, wherein said antigen has a sequence encoded by the complement of the nucleic acid.

Group XXIII, claim(s) 33,34,35,36, 53-55, drawn to drawn to a method of diagnosing a disease, comprising detecting a cytotoxic or T helper lymphocyte specific to the tumor associated antigen, wherein said antigen has a sequence encoded by the complement of the nucleic acid.

Group XXIV, claim(s) 44,45,47-49,53-55, drawn to a method for determining regression, course or onset of a disease, comprising monitoring a sample for the amount of nucleic acid, which encodes a tumor associated antigen, wherein said antigen has a sequence encoded by a nucleic acid.

Group XXV, claim(s) 44,45,50,53-55, drawn to a method for determining regression, course or onset of a disease, comprising monitoring a sample for the amount of tumor associated antigen, wherein said antigen has a sequence encoded by a nucleic acid.

Group XXVI, claim(s) 44,45,51,53-55, drawn to a method for determining regression, course or onset of a disease, comprising monitoring a sample for the amount of antibodies that bind to a tumor associated antigen, wherein said antigen has a sequence encoded by a nucleic acid.

Group XXVII, claim(s) 44,45,52,53-55, drawn to a method for determining regression, course or onset of a disease, comprising monitoring a sample for the amount of cytotoxic or T helper

lymphocytes specific to the tumor associated antigen, wherein said antigen has a sequence encoded by a nucleic acid.

Group XXVIII, claim(s) 44,45,47-49,53-55, drawn to a method for determining regression, course or onset of a disease, comprising monitoring a sample for the amount of nucleic acid, which encodes a tumor associated antigen, wherein said antigen has a sequence encoded by the complement of the nucleic acid.

Group XXIX, claim(s) 44,45,50,53-55, drawn to a method for determining regression, course or onset of a disease, comprising monitoring a sample for the amount of tumor associated antigen, wherein said antigen has a sequence encoded by the complement of the nucleic acid.

Group XXX, claim(s) 44,45,51,53-55, drawn to a method for determining regression, course or onset of a disease, comprising monitoring a sample for the amount of antibodies that bind to a tumor associated antigen, wherein said antigen has a sequence encoded by the complement of the nucleic acid.

Group XXXI, claim(s) 44,45,52,53-55, drawn to a method for determining regression, course or onset of a disease, comprising monitoring a sample for the amount of cytotoxic or T helper lymphocytes specific to the tumor associated antigen, wherein said antigen has a sequence encoded by the complement of the nucleic acid.

Group XXXII, claim(s) 46, drawn to a method for determining regression, course or onset of a disease, comprising monitoring a sample for the amount of two or more nucleic acids which encode two or more different tumor-associated antigens.

Group XXXIII, claim(s) 46, drawn to a method for determining regression, course or onset of a disease, comprising monitoring a sample for the amount of two or more different tumor-associated antigens.

Group XXXIV, claim(s) 46, drawn to a method for determining regression, course or onset of a disease, comprising monitoring a sample for the amount of two or more antibodies that bind two or more different tumor-associated antigens.

Group XXXV, claim(s) 46, drawn to a method for determining regression, course or onset of a disease, comprising monitoring a sample for the amount of two or more cytotoxic or T helper lymphocytes specific to two or more different tumor-associated antigens.

Group XXXVI, claim(s) 56, drawn to a method of treating disease characterized by expression or abnormal expression of a tumor-associated antigen, wherein said antigen has a sequence encoded by a nucleic acid.

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Group XXXVII, claim(s) 56, drawn to a method of treating disease characterized by expression or abnormal expression of a tumor-associated antigen, wherein said antigen has a sequence encoded by the complement of the nucleic acid.

Group XXXVIII, claim(s) 57-60, drawn to a method of treating, diagnosing or monitoring a disease, comprising administering an antibody binding to a tumor-associated antigen, wherein said antigen has a sequence encoded by a nucleic acid.

Group XXXIX, claim(s) 57-60 drawn to drawn to a method of treating, diagnosing or monitoring a disease, comprising administering an antibody binding to a tumor-associated antigen, wherein said antigen has a sequence encoded by the complement of the nucleic acid.

Group XL, claim(s) 61-63, drawn to a method of treating a patient characterized by expression or abnormal expression of a tumor-associated antigen, comprising removing immuno-reactive cells from a patient, contacting the cells with said tumor-associated antigen and reintroducing the cells into the patient, wherein said antigen has a sequence encoded by a nucleic acid.

Group XLI, claim(s) 61-63, drawn to a method of treating a patient characterized by expression or abnormal expression of a tumor-associated antigen, comprising removing immuno-reactive cells from a patient, contacting the cells with said tumor-associated antigen and reintroducing the cells into the patient, wherein said antigen has a sequence encoded by the complement of the nucleic acid.

Group XLII, claim(s) 64-67, drawn to a method of treating a patient characterized by expression or abnormal expression of a tumor-associated antigen, comprising transfecting a host cell with a nucleic acid, culturing the cell and introducing the cell into a patient, wherein said antigen has a sequence encoded by a nucleic acid.

Group XLIII, claim(s) 64-67, drawn to a method of treating a patient characterized by expression or abnormal expression of a tumor-associated antigen, comprising transfecting a host cell with a nucleic acid, culturing the cell and introducing the cell into a patient, wherein said antigen has a sequence encoded by the complement of the nucleic acid.

Group XLIV, claim(s) 69-71, drawn to drawn to a method of treating a patient characterized by expression or abnormal expression of a tumor-associated antigen, comprising identifying cells from the patient which express abnormal amounts of the tumor-associated antigen, isolating the cells, culturing the cells and introducing the cells into a patient, wherein said antigen has a sequence encoded by a nucleic acid.

Group XLV, claim(s) 69-71, drawn to drawn to a method of treating a patient characterized by expression or abnormal expression of a tumor-associated antigen, comprising identifying cells from the patient which express abnormal amounts of the tumor-associated antigen, isolating the

cells, culturing the cells and introducing the cells into a patient, wherein said antigen has a sequence encoded by the complement of the nucleic acid.

Group XLVI, claim(s) 73,75-78, drawn to a nucleic acid selected from a group.

Group XLVII, claim(s) 73,75-78, drawn to a nucleic acid that is the complement of one selected from the group.

Group XLVIII, claim(s) 74-78, drawn to a nucleic acid that codes for a protein or polypeptide comprising an amino acid sequence one selected from the group of SEQ ID No.s 10, and 12-14, a part or derivative thereof.

Group XLIX, claim(s) 82, drawn to a protein or polypeptide selected from the group of claim 73

Group L, claim(s) 83-85, drawn to a protein or polypeptide comprising an amino acid sequence one selected from the group of SEQ ID No.s 10, and 12-14, a part or derivative thereof.

Group LI, claim(s) 86,87,93,94, drawn to an agent which binds specifically to a protein or polypeptide encoded by a nucleic acid

Group LII, claim(s), 86,87,93,94 drawn to an agent which binds specifically to a protein or polypeptide encoded by the complement of a nucleic acid

Group LIII, claim(s) 88-92 , drawn to an antibody

Group LIV, claim(s) 93,94, drawn to a conjugate comprising and agent or antibody and a therapeutic or diagnostic agent.

Group LV, claim(s) 98 drawn to a recombinant DNA molecule

These groups encompass a plethora of different polynucleotide and polypeptide sequences. Depending on the group elected from those above, applicant is further **REQUIRED** to elect a single specific polynucleotide or polypeptide sequence for prosecution from those listed in the relevant claims. This is a **RESTRICTION BY ELECTION** and not a species election.

The inventions listed as Groups I-LV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Inventions I-LV lack a unifying special technical feature. Applicant provided reference

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International Application WO 99/64452 (16.12.99) discloses GPR35A polypeptides, methods for making such polypeptides by recombinant means, and using such polypeptides (Abstract).

Since the claimed subject matter was known from the prior art document of International Application WO 99/64452, the subject matters of claims 1-28, 32-40, 42-67, 69-71, 73-78, 82-94, and 98 are not so linked as to form a single general inventive concept (Rule 13.1 PCT) as they appear not to be linked by a new and inventive common special technical feature in the sense of Rule 13.2 PCT by taking into account the state of the art.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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